

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

<p>NIPPON SHINYAKU CO., LTD., Plaintiff,</p> <p>v.</p> <p>SAREPTA THERAPEUTICS, INC., Defendant.</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	<p>C.A. No. 21-1015 (JLH)</p>
<p>SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs</p> <p>v.</p> <p>NIPPON SHINYAKU CO., LTD. And NS PHARMA, INC., Plaintiff/Counter Defendants.</p>	<p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p> <p>)</p>	

**NS'S RESPONSE TO *DAUBERT* MOTION NO. 1
TO EXCLUDE TESTIMONY AND OPINIONS OF SCOTT E. KAMHOLZ**

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Dated: January 12, 2024

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I INTRODUCTION

Defendant-Counterclaim Plaintiffs Sarepta Therapeutics, Inc. and the University of Western Australia’s (together, “Sarepta”) motion to exclude the opinions and testimony of Nippon Shinyaku Co. Ltd.’s (“NS”) expert Scott E. Kamholz on Patent and Trademark Office practice and procedure should be denied. Sarepta’s motion is based on demonstrably incorrect interpretations of Dr. Kamholz’s opinions regarding the UWA Patents. Contrary to Sarepta’s assertions, Dr. Kamholz expressly stated both in his expert reports and at his deposition that he was *not* offering opinions on the named inventors’ state of mind, technical opinions, or what the examining attorney would have done. Because these are Sarepta’s only arguments for excluding Dr. Kamholz, its motion to exclude Dr. Kamholz’s opinions relating to the UWA Patents should be denied.

Further, even though Sarepta addresses only Dr. Kamholz’s opinions regarding the UWA Patents, they seek to preclude Dr. Kamholz from providing opinions related to NS’s patents as well. D.I. 395 (Sarepta Br. ISO Daubert Motions) at 3 (Dr. Kamholz “should be precluded from providing any testimony at all.”). The Court should firmly reject Sarepta’s attempted overreach. Even if the Court excludes all or part of Dr. Kamholz’s opinions relating to the UWA patents, he should be allowed to testify regarding the NS Patents.

II ARGUMENT

A. Dr. Kamholz’s Opinions Are Helpful to the Factfinder

Dr. Kamholz’s opinions based on his experience as a patent agent, patent attorney, and administrative patent judge that would be helpful to the factfinder determine materiality in the context of PTO practice and procedure. *See, e.g., Persawvere, Inc. v. Milwaukee Electric Tool Corp.*, C.A. No. 21-400-GBW (D. Del. Nov. 20, 2023), at *28-30 (denying motion to exclude former administrative patent judge’s opinions regarding materiality); *W.R. Grace & Co. v. Elysium Health, Inc.*, C.A. No. 20-1098-GBW-JLH (D. Del. Aug. 3, 2023), at *7. These opinions relating to the UWA

Patents include (by way of example only):

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

For example, Dr. Kamholz can explain that [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] In another example, Dr. Kamholz can explain that while actual reduction to practice is not required for a patent, when an applicant represents that an actual reduction to practice has occurred, that triggers additional obligations to investigate and confirm accuracy under PTO practice and procedure. Accordingly, Dr. Kamholz should be allowed to testify concerning why information would be material based on PTO practices and procedures.

B. Dr. Kamholz Has Not Offered Technical Opinions or Opinions On State of Mind

Sarepta argues that Dr. Kamholz provides expert opinions on technical matters. D.I. 395 at 7-8. However, this argument does not provide a basis for excluding Dr. Kamholz's opinions because it

is based on a false premise. Dr. Kamholz has expressly disclaimed offering technical opinions. D.I. 425-1 (Ex. 26) Kamholz Reply ¶¶ 4-5; NS Ex. 48 (Kamholz Dep.) at 86:18-87:21.

Similarly, Sarepta attempts to twist Dr. Kamholz's use of the phrase "knew or should have known" into something it is not: an opinion concerning the UWA inventors' and prosecuting attorney's state of mind. D.I. 395 at 4. As Dr. Kamholz explained at his deposition, he is *not* offering opinions as to Stephen Wilton or Sue Fletcher's actual knowledge when they signed the inventorship declarations submitted to the PTO in connection with the UWA patents, or prosecuting attorney Amy Mandragouras's knowledge at the time she submitted those declarations. NS Ex. 48 (Kamholz Dep.) at 50:3-14, 51:4-7. His opinions are that [REDACTED]

[REDACTED] NS Ex. 48 (Kamholz Dep.) at 48:3-23, 49:8-50:2, 50:13-51:3 (discussing D.I. 425-1 (Ex. 24) Kamholz Opening ¶¶ 32, 33). Dr. Kamholz does not [REDACTED] NS Ex. 48 (Kamholz Dep.) at 49:3-7; D.I. 425-1 (Ex. 26) at Kamholz Reply ¶¶ 17, 30. This is proper because it is for the Court to decide whether the evidence shows [REDACTED]

[REDACTED] Dr. Kamholz does not offer the ultimate opinion as to [REDACTED] [REDACTED] as is proper because that is the province of the Court. NS Ex. 48 (Kamholz Dep.) at 78:25-80:8.

Dr. Kamholz's opinions are admissible precisely because he respected the boundaries of proper expert opinion and did not offer an opinion on the ultimate conclusion. Thus, contrary to Sarepta's motion, Dr. Kamholz's "knew or should have known" opinions are not fatal to admissibility of his testimony and opinions. D.I. 395 at 4. Those opinions deliberately leave it to the Court to decide that

[REDACTED]

[REDACTED]

As discussed in NS's Response to Sarepta's Motion for Summary Judgment #3 of No Inequitable Conduct filed contemporaneously herewith, there is sufficient evidence for the Court to determine that [REDACTED]

[REDACTED]

C. Sarepta's Extraordinary Request to Preclude Dr. Kamholz from Testifying Altogether is Wholly Unsupported

Finally, as demonstrated above, Sarepta baldly seeks relief that far exceeds the scope of its argument: that the Court exclude Dr. Kamholz's testimony in its entirety. D.I. 395 at 8. This relief is unwarranted, particularly because Dr. Kamholz offers opinions in his Rebuttal Report regarding NS's patents that Sarepta completely fails to address in its brief.

III CONCLUSION

The Court should deny Sarepta's motion to preclude Dr. Kamholz.

Dated: January 12, 2024

Respectfully submitted,

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